

REMARKS

Claims 48-51, 61, 134, 136, 139, 141, 142, 147 and 150-156 have been canceled to expedite prosecution. Claims 52, 57, 67, 69, 140, 148 and 149 have been amended for greater clarity. Claims 57 and 60 were identical, prior to the amendment to Claim 57.

Rejection of Claims 48-52, 134 and 148-156 Under 35 U.S.C. § 112, First Paragraph

Claims 48-52, 134 and 148-156 have been rejected under 35 U.S.C. § 112, first paragraph, as it is said that the specification does not reasonably provide enablement for nucleic acids with indeterminate sequence identity to SEQ ID NO:5 or SEQ ID NO:7 or allelic variants or variant alleles of SEQ ID NO:5 or SEQ ID NO:7, or methods of detecting allelic variants of SEQ ID NO:5 or SEQ ID NO:7, without specifying the exact sequence variation detected or the probe required.

Claims 48-51, 134 and 150-156 have been canceled. Claims 52, 148 and 149 have been amended to clarify their meaning. Claim 52 now includes hybridization conditions that define the degree of sequence relatedness of the isolated nucleic acid to SEQ ID NO:5 or its complement, such that one of ordinary skill in the art could carry out such hybridization and determine which isolated nucleic acids are included within Claim 52. Claims 148 and 149 have been amended so that SEQ ID NO:7 is the reference sequence to which the DNA of a test sample is compared. For example, one of ordinary skill in the art, using known methods, could readily obtain the sequence of DNA isolated from a test sample and compare it with SEQ ID NO:7. Other methods of comparing sequence information of one nucleic acid molecule to another nucleic acid molecule are known to those of skill in the art. Such methods have been used to identify an individual as distinguished from another, to determine paternity of an individual, and to look for a mutation that could define a genetic defect. See, for example, page 46, line 21 to page 47, line 7, and page 13, lines 20-27. Applicants have previously reported the description of a variant allele associated with hemachromatosis (Montosi *et al.*, *J. Clin. Invest.* 108(4):619-623, 2001).

Rejection of Claims 51, 134, 148, 149, 152-154 Under 35 U.S.C. § 112, First Paragraph

Claims 51, 134, 148, 149, 152-154 have been rejected under 35 U.S.C. § 112, first paragraph, as “containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.”

Claims 51, 134, and 152-154 have been canceled. Claims 148 and 149 have been amended to bring greater clarity to their meaning.

The Examiner sets forth the reasoning of the rejection as essentially that the polynucleotides of the claims are not described with sufficient detail of structure or characteristics to show that Applicants were in possession of the invention. Claims 148 and 149 have been amended to make clear that the reference DNA to which the test sample DNA is to be compared is SEQ ID NO:7, which is described in the specification. For Claims 148 and 149, the nucleotide sequence of the test sample DNA need not be known initially and need not be described in order for one of ordinary skill in the art to carry out the method. One of ordinary skill in the art, knowing the DNA sequences described in the specification, could obtain isolated DNA of a *ferroportin1* gene and compare the sequence to SEQ ID NO:7 to detect a variant allele.

Rejection of Claims 49, 51, 52, 67, 69, 70, 71, 140, 152, and 153 Under 35 U.S.C. § 112, Second Paragraph

Claims 49, 51, 52, 67, 69, 70, 71, 140, 152, and 153 have been rejected under 35 U.S.C. § 112, second paragraph, as being “indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.”

Claims 49, 51, 52, 69, 152 and 153 are said to be indefinite because of the term *high stringency conditions*. Claims 49, 51, 152 and 153 have been canceled. Claims 52 and 69 have been amended to define high stringency conditions of nucleic acid hybridization in terms understood by one of ordinary skill in the art. The amendments are taken from page 12, lines 15-20.

Claims 67, 70 and 71 are said to be indefinite, as “the claimed invention is directed to subject matter which is indefinite and may encompass naturally-occurring subject matter.” Claim 67 has been amended to describe the nucleic acid in the cultured cell as being

recombinant. The amendment of Claim 67 should obviate the rejection of Claims 70 and 71, as they are dependent on Claim 67.

Claim 140 is said to be indefinite in scope, as it is said to include terms with a broad range and a narrow limitation. Claim 140 has been amended to clarify its meaning.

Rejection of Claims 135, 136, 138, 141, 142 and 147 Under 35 U.S.C. § 102(b)

Claims 135, 136, 138, 141, 142 and 147 have been rejected under 35 U.S.C. § 102(b), as they are said to be unpatentable over Dodsworth et al. (1995, Accession No. HS153B8F). Claims 136, 141, 142 and 147 have been canceled. Claims 135 and 138 are drawn to nucleic acids that are 15 to 30 nucleotides. The nucleic acid of Dodsworth et al. is 260 nucleotides. The nucleic acid of Dodsworth et al. does not anticipate Claims 135 and 138, as it does not meet all the limitations of the claims.

Interview Summary

Applicants wish to thank Examiner Sandra Wegert and Primary Examiner Elizabeth Kemmerer for the interview on 21 December 2004 with Attorneys Carol Egner and Doreen Hogle. The discussion was limited to Claims 148 and 149, and the grounds for rejection of these claims.

Claims 148 and 149 have been rejected under 35 U.S.C. § 112, first paragraph, as it is said that the specification does not reasonably provide enablement for the method. The discussion of the reasons for rejection in the Office Action focused on the Examiner's belief that the specification does not sufficiently identify variant alleles of a *ferroportin1* gene, and further, that due to lack of guidance on the function of polypeptides encoded by the variant alleles, one of ordinary skill in the art would lack sufficient guidance to make and use the claimed invention.

As discussed above, Applicants proposed amendments to Claims 148 and 149 that would define the reference DNA as SEQ ID NO:7, so that the DNA sequence of isolated DNA of a test sample would be compared to the DNA sequence SEQ ID NO:7 as presented in the specification.

Applicants presented the reasoning that for the method of Claims 148 and 149, one of ordinary skill in the art would have available in the prior art methods to identify a human *ferroportin1* gene, to isolate the DNA, and to obtain sequence information for the isolated DNA.

Applicants further explained that the method of Claims 148 and 149 has known uses, as similar methods have been applied to other genes for the identification of individuals, determination of paternity, and testing a gene to determine whether it has a mutation possibly associated with a genetic disease.

Claims 148 and 149 have been rejected under 35 U.S.C. § 112, first paragraph, as “containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.” The discussion presented by the Examiner in the Office Action emphasized that to describe a variant allele, the structural characteristics, and in particular, a nucleotide sequence, should be given in the specification.

Applicants responded to this rejection with the reasoning that for the method of Claims 148 and 149, no prior knowledge of the variant allele is necessary to carry out the method. The method of Claims 148 and 149 can be carried out using known methods which do not require any prior knowledge of the DNA sequence of the test DNA or of any particular allele. The end point of the method is determining whether DNA in a test sample differs from SEQ ID NO:7, a sequence fully described in the specification.

CONCLUSION

The Examiner is requested to consider the above amendments and remarks, and to reconsider the rejections. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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